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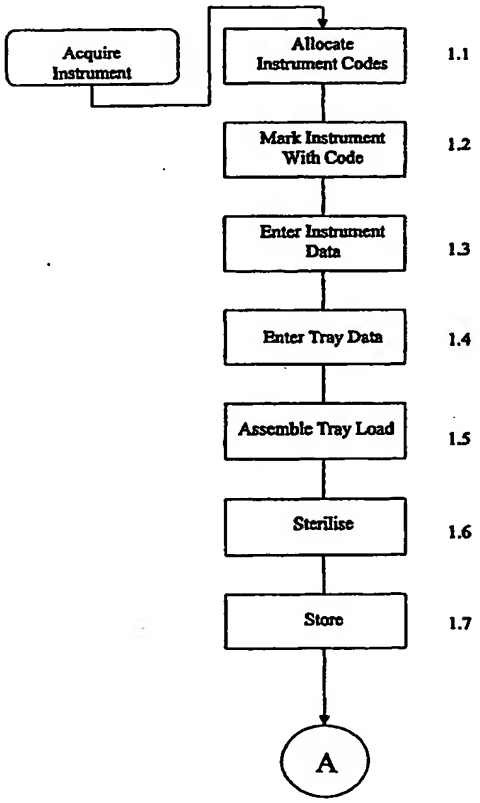
(54) Title: PROCESS OF AND APPARATUS FOR MANAGEMENT OF SURGICAL INSTRUMENTS, PROSTHESES, MEDICAL CONSUMABLES AND THE LIKE

(57) Abstract

A surgical instrument management system allocates identification codes to surgical instruments, prosthetic devices and categories of surgical consumables. Data relating to use; sterilisation and repair of surgical instruments is tracked in a central database. Data relating to costs of instruments, prostheses and consumables are also entered in the database. The system tracks usage and can identify when reusable disposable instruments should be disposed of; and when maintenance of instruments is due. Costs of instruments and of surgical consumables can also be attributed to a surgical procedure.



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Title of Invention:

Process of and Apparatus for Management of Surgical Instruments, Prostheses, Medical Consumables and the Like

Technical Field:

This invention is in the technical field of surgical instruments, prostheses, medical consumables and the like.

Background Art:

Throughout this specification:

the terms 'surgery' is used to include any organisation or institution in which surgery or similar procedures are carried out on persons, animals, or plants and includes hospitals, dental and veterinary surgeries and biological research institutes;

the term 'surgical instrument' includes instruments used in dentistry, in veterinary surgery or in biological research; and

the term 'patient' includes a person, an animal or a plant.

Traditionally surgical instruments have been simple mechanical devices such as scalpels, scissors, retractors and the like. Such instruments are generally composed of stainless steel. Surgical instruments must be cleaned after each use to remove blood, tissue and other biological contaminants (referred to as 'biological burden'), sterilised, and then stored in sterile conditions ready for the next use. Surgical instruments are generally arranged for use in a collection of instruments on a tray, with the contents of the tray tailored to a particular surgical procedure.

The traditional stainless steel instruments are robust and are unlikely to deteriorate significantly during the sterilisation process.

Stainless steel instruments developed more recently for microsurgery tend to have thin sections and delicate parts. These instruments are more prone to damage by handling in

use, cleaning and sterilisation. Although they are of stainless steel, because they are thin in section they are more readily damaged by corrosion.

Other recently developed surgical instruments such as endoscopes, laparoscopes and the like are composed in whole or in part of plastics materials which may deteriorate because of the relatively high temperatures used during sterilisation. The deterioration of plastics insulating material in modern surgical instruments can result in death or serious injury to a patient during surgery.

Some of these modern surgical instruments are classed by the manufacturer as 're-useable disposable' instruments. These instruments are designed to be used in a specific number of procedures and then discarded. It is thus necessary to keep track of the number of uses of each such instrument so that the instrument can be discarded when it has been used for the specified number of procedures.

It also tends, in general, to be more difficult to remove biological burden from these modern types of instruments. Although the sterilisation process is capable of sterilising material within biological burden, the greater the degree of that biological burden then the greater the risk of ineffective sterilisation.

Ineffective sterilisation of surgical instruments can result in patient-to-patient transmission of infections. Suspected patient-to-patient transmission of infection by an instrument during surgery casts doubt on the effectiveness of the sterilisation of all the instruments treated in the same batch. It is thus desirable that a hospital be able to recall and re-sterilise all the instruments which were treated in the suspect batch. It is also desirable that a hospital be able to identify all patients on whom a particular surgical instrument may have been used.

It is similarly desirable that a hospital be able to identify all patients who have received a prosthesis from a particular manufacturing batch, or who have received a particular prosthesis.

Modern surgical instruments tend to require more maintenance than do traditional metal devices. For example, modern instruments may require programmed re-testing of insulation resistance or replacement of parts. Maintenance and capital costs of these modern instruments tend to be high, and it is desirable that these costs be attributed (for billing purposes) to each surgical procedure performed on a patient. It is similarly desirable that the costs of consumables and prostheses which are used during a surgical procedure be attributed to the procedure and billed to the patient.

Summary of the Invention:

This invention accordingly provides a surgical instrument management system for the management of the use of surgical instruments within a surgery, which system includes the steps of:

allocating to each surgical instrument an identification code which is unique within that surgery; and

recording within a database:

the identification code which has been allocated to that surgical instrument;

information relating to each use of each surgical instrument on a patient; and

information relating to each sterilisation of each surgical instrument

Preferred Features of the Invention

Preferably, the information that is recorded within the database for each use of each surgical instrument includes information which identifies the patient on whom the instrument was used.

Preferably each surgical instrument is marked with a marking which indicates the identification code which has been allocated to that surgical instrument.

A group of surgical instruments which are specific to a particular surgical procedure may be located together on a tray and sterilised together on that tray. In such a case, the information recorded in the database preferably includes, for each sterilisation of each

such tray of instruments, information indicating each instrument which was located on the tray.

Preferably, the invention also provides means for extracting from the database information indicating the number of times that a surgical instrument has been sterilised and used in procedures on patients.

Preferably, the system further includes the steps of:

allocating to each prosthesis which is to be used in a surgical procedure within the surgery an identification code which is unique within that surgery; and

recording within the database:

the identification code which has been allocated to that prosthesis; and

information relating to the patient who has received the prosthesis.

In order that the present invention may be more readily understood, preferred embodiments of it will now be described with reference to the accompanying drawings.

Brief Description of the Drawings:

Figures 1A and 1B together comprise a top-level process flow chart illustrating the operation of the surgical instrument management system.

Detailed Description of the Preferred Embodiments:

The surgical instrument management system according to one aspect of the present invention is illustrated by the top-level process flow chart of Figures 1A and 1B. The sub-processes which are illustrated in Figure 1A are followed on initial implementation of the present invention in a surgery, and on each subsequent acquisition of an instrument.

The sub-processes illustrated in Figure 1B are applicable to the subsequent use of each instrument.

Sub-process 1.1 requires the allocation of a code to each instrument. This code is unique to each instrument used within the surgery. Preferably, this code includes a component which is unique to the surgery within which the instrument is to be used.

It is also preferred that, in sub-process 1.1, a unique code be allocated to each prosthetic device to be used within the surgery. Manufacturers of prostheses generally allocate a batch number and serial number to prostheses. If the manufacturer has allocated a serial number to a particular prosthesis, that serial number is allocated as the unique code for the prosthesis. If the manufacturer has not allocated a serial number, then a unique code is allocated.

It is similarly preferred that during sub-process 1.1 a unique code is allocated to each category of consumable that is used during surgical procedures.

In sub-process 1.2, each instrument is relatively permanently marked with its unique code. A preferred method of marking codes is salt etching the code onto the instrument. In Australia, it is preferred that such etching be in accordance with Australian Standard 4187.

It is also preferred that during sub-process 1.2 the packaging of each prosthetic device is marked with its unique code. It is similarly preferred that the packaging of each item of consumables be marked with the unique code that indicates the category to which the item belongs.

In sub-process 1.3, data relating to each instrument is entered into a database. That data includes the unique code that identifies the instrument. In cases where the instrument is a re-useable disposable instrument, it is preferred that this data include data which indicates the effective serviceable life of the instrument. The effective useable life of re-useable disposable instrument is generally specified by the manufacturer in terms of the number of times that the instrument may be sterilised before it must be discarded. In the cases of other instruments, it is preferred that this data include the number of times that the instrument may be used before it should be serviced.

It is also preferred that, during sub-process 1.3, data be entered about the capital cost of each instrument and about the rate at which that capital cost is to be recovered in respect of each procedure in which the instrument is used.

It is also preferred that data relating to each prosthetic device be entered into the database in sub-process 1.3. This data includes the unique code which identifies the device, and preferably includes data indicating any one or more of the manufacturer, the supplier, the manufacturer's batch number, and the cost of the device.

It is also preferred that data relating to each category of consumable be entered into the database in sub-process 1.3. This data includes the unique code which identifies the category of data, and preferably includes unit cost.

In sub-process 1.4, tray data is entered into the database. This data identifies the specific instruments which must be assembled together on each tray. The tray data includes, for each instrument, the unique code which was allocated to that instrument in sub-process 1.1.

It is preferred that the tray data includes data which can be used in training operators on the assembly of a tray. A particularly preferred form of such data is a multi-media presentation illustrating the assembly of instruments onto the tray.

In sub-process 1.5, the load for a tray is assembled onto that tray in accordance with the relevant tray data that was entered into the database in sub-process 1.4.

During this tray assembly sub-process, a unique tray load identifier code is generated. A label or other substrate bearing a machine-readable indicator of this code is produced and preferably is fixed to the packaging of the tray. Alternatively, it may be fixed direct to the tray. This indicator is also scanned to read the code which identifies the tray.

The number of times that each instrument has been used is also examined during this tray assembly process. Preferably, the act of generating the unique tray load identifier code indexes a count of the number of times that each instrument in the tray load has been used. Each disposable instrument which has reached the end of its service life is flagged to the operator, who substitutes that instrument with another instrument and who updates the tray data to indicate that one of the instruments for the tray has been changed. Similarly, it is preferred that each instrument which has been used the number of times allowed before servicing is required is serviced and either replaced on the tray or substituted by another instrument. In the case where the instrument is substituted, the operator updates the tray data to indicate that one of the instruments for the tray has been changed.

It is preferred that a checklist, listing all instruments on the tray, is printed and associated with the tray.

In sub-process 1.6, the assembled tray of instruments is sterilised in known manner. During process 1.6, data is entered into the database to identify each tray being sterilised, the steriliser, and the steriliser batch. Preferably, this data entry takes place by scanning bar coded labels. In a most preferred form of the invention, the data entry takes place by scanning bar codes with a hand-held scanner. It is preferred that the scanner be programmed to prompt the operator to first enter the steriliser where the data entry is taking place. The operator then enters a steriliser identifier by scanning a bar code. Referential integrity checking then takes place within the scanner to ensure that a steriliser code has been scanned, and not a code for some other entity (such as for a surgical tray). Once a steriliser code has successfully been scanned, it is preferred that the operator is then prompted to enter an operator's bar code. Again, referential integrity checking takes place in the scanner to ensure that it is an operator's bar code which has been scanned. The other data indicating the trays being sterilised is similarly entered.

In sub-process 1.7, the sterilised trays of instruments are stored in sterile stores in known manner. Preferably during this sub-process data is entered in the database to identify the

sterile store in which the tray is being stored by scanning both a bar-coded label identifying the store and the bar coded label associated with the tray.

In sub-process 1.8, a tray of instruments which has been removed from a sterile store is used in the course of a surgical procedure. Before the instruments are used, the codes identifying the patient and the tray of instruments are entered into the database. Preferably, the code identifying the patient is printed by the hospital admissions staff at the time of admission of the patient and is fixed to the patient's wristband.

Preferably information identifying any one or more of the surgical and nursing staff, and the date of the procedure, and the location of the procedure within the surgery are also entered.

Preferably, this data entry takes place by scanning bar coded labels. In a most preferred form of the invention, the data entry takes place by scanning bar codes with a hand-held scanner. It is preferred that the scanner be programmed to prompt the operator to first enter the location where the scanning is taking place. The operator then enters, for example, an operating theatre identifier by scanning a bar code. Referential integrity checking then takes place within the scanner to ensure that a location code has been scanned, and not a code for some other entity (such as for a surgical tray). Once a location code has successfully been scanned, it is preferred that the operator is then prompted to enter a patient bar code. Again, referential integrity checking takes place in the scanner to ensure that it is a patient bar code which has been scanned. The other data (such as for surgical staff, nursing staff, trays, prostheses and consumables) are similarly entered and checked for accuracy.

In cases where data entry takes place by scanning with a hand held scanner, the data is later down-loaded from the scanner into the database. It is preferred that the data be down-loaded by docking the scanner in a docking station which is associated with a personal computer (PC).

During sub-process 1.9 and 1.10, each instrument is cleaned and inspected in known manner. At sub-process 1.11, a decision is made (based on inspection 1.10) whether or not the instrument is still serviceable.

If the instrument is still serviceable, it proceeds through the previously described sub-processes 1.5 (assembly on tray), 1.6 (sterilise) and 1.7 (store in sterile store).

If sub-process 1.11 decides that the instrument is not serviceable, then a decision is made at process 1.12 whether or not to repair the instrument. If it is decided not to repair the instrument, then it is discarded.

If the decision is to repair the instrument, then the instrument is repaired and data about the repairs is entered into the database. It is also preferred that the data which is entered at this process includes data about the cost of repairing the instrument. Once the instrument has been repaired, it is assembled onto a tray according to the previously described sub-process 1.5.

It is also preferred that the overall system includes a sub-process (not illustrated) in which the database can be interrogated to ascertain an apportionment of instrument capital and repair costs which are attributable to each surgical procedure which has taken place.

It is also preferred that the overall system includes processes (not illustrated) by which the database may be interrogated to establish any common feature between patients. For example, if it turns out that a particular patient is infected with a particular disease, it is preferred that there be processes for interrogating the database to establish whether that infection may have been transmitted patient-to-patient by an inadequately sterilised instrument, or in a contaminated operating theatre, or the like.

It is also preferred that each unique code which is allocated to an entity includes a sub-code which indicates the type of entity. According to such embodiments of the invention, the computer software of the management system includes a number of modules. One such module is an input module which monitors data input. This module examines data

input, and identifies from the sub-code the type of entity in respect of which data has been entered. Other modules include various registers, for example a stores register. There is also a module for the main management module. The modules work together so that when the input module identifies the type of entity, that module then:

interrogates the appropriate module to obtain data about that entity; and

then transfers that data to the main management module.

For example, on input of the scanned data 'ST0014', data input module identifies the data as being staff data and interrogates the appropriate module to obtain the data 'Mary James, Scout Nurse'. The input module then transfers this data to the main management module.

In an especially preferred embodiment of the invention, the types of codes allocated include a alphabetic prefix indicating the type of entity. A preferred form of coding according to this embodiment, the categories of codes, and specific examples of a code allocated to an entity, include:

staff barcode, eg ST0014

prosthetic barcode, eg PO0188

sterile item barcode, eg TY10509

equipment barcode, eg AO00111

stores barcode, eg SW001168

surgical area barcode, eg OP00164

operation type barcode, eg PP00678

patient number barcode, eg UR12389

and steriliser barcode, eg SO0169

Claims

1. A surgical instrument management system for the management of the use of surgical instruments within a surgery, which system includes the steps of:

allocating to each surgical instrument an identification code which is unique within that surgery; and

recording within a database:

the identification code which has been allocated to that surgical instrument;

information relating to each use of each surgical instrument on a patient; and

information relating to each sterilisation of each surgical instrument

2. A surgical instrument management system as claimed in claim 1 wherein at least one surgical instrument is marked with a marking which indicates the identification code which has been allocated to that surgical instrument.

3. A surgical instrument management system as claimed in claim 1 or claim 2 further including, for each surgical instrument, entering into the database data about:

the capital cost of the instrument; and

the rate at which the capital cost of the instrument is to be recovered in respect of each procedure.

4. A surgical instrument management system as claimed in any one of the preceding claims, further including the steps of, for each prosthetic device which is to be used within the surgery:

allocating a unique code to the prosthetic device; and

recording that unique code within the database.

5. A surgical instrument management system as claimed in claim 4 further including, for each prosthetic device, entering data about the cost of the prosthesis into the database.

6. A surgical instrument management system as claimed in any one of the preceding claims, further including the steps of, for each category of consumable that is to be used during surgical procedures:

allocating a unique code to the category of consumable; and

recording that unique code within the database.

7. A surgical instrument management system as claimed in claim 6, further including entering data into the database about the unit cost of each category of consumable.

8. A surgical instrument management system as claimed in any one of the preceding claims wherein the information that is recorded within the database for each use of each surgical instrument includes information which identifies the patient on whom the instrument was used.

9. A surgical instrument management system as claimed in any one of the preceding claims where the information that is recorded within the database for each use of each surgical instrument includes information which identifies at least one of:

the location within the surgery at which that use takes place;

the patient on whom the instrument is used;

the identities of the surgical staff who conduct the surgical procedure; and

the identities of any other staff present.

10. A surgical instrument management system as claimed in any one of the preceding claims wherein a group of surgical instruments which are specific to a particular surgical procedure are located together on a tray and sterilised together on that tray.

11. A surgical instrument management system as claimed in claim 10 wherein the information recorded in the database includes, for each sterilisation of each such tray of instruments, information indicating each instrument which was located on the tray.

12. A surgical instrument management system as claimed in any one of the preceding claims, further including means for extracting from the database information indicating

the number of times that a surgical instrument has been sterilised and used in procedures on patients.

13. A surgical instrument management system as claimed in any one of the preceding claims, further including the steps of:

allocating to each prosthesis which is to be used in a surgical procedure within the surgery an identification code which is unique within that surgery; and

recording within the database:

the identification code which has been allocated to that prosthesis; and

information relating to the patient who has received the prosthesis.

14. A surgical instrument management system as claimed in any one of the preceding claims, wherein each code includes a sub-code which identifies the category of entity to which the code has been allocated.

15. A surgical instrument management system as claimed in claim 15, further including:

a main management software module;

a data input software module; and

at least two register modules,

wherein the data input module is adapted:

to identify, from the sub-code of an item of input data, the appropriate register module to interrogate to obtain further data related to the input data; and

to transfer that further data to the main management software module.

16. A surgical instrument management system as claimed in any one of the preceding claims, substantially as described with reference to the drawings.

17. A surgical instrument management system, substantially as described with reference to the drawings.

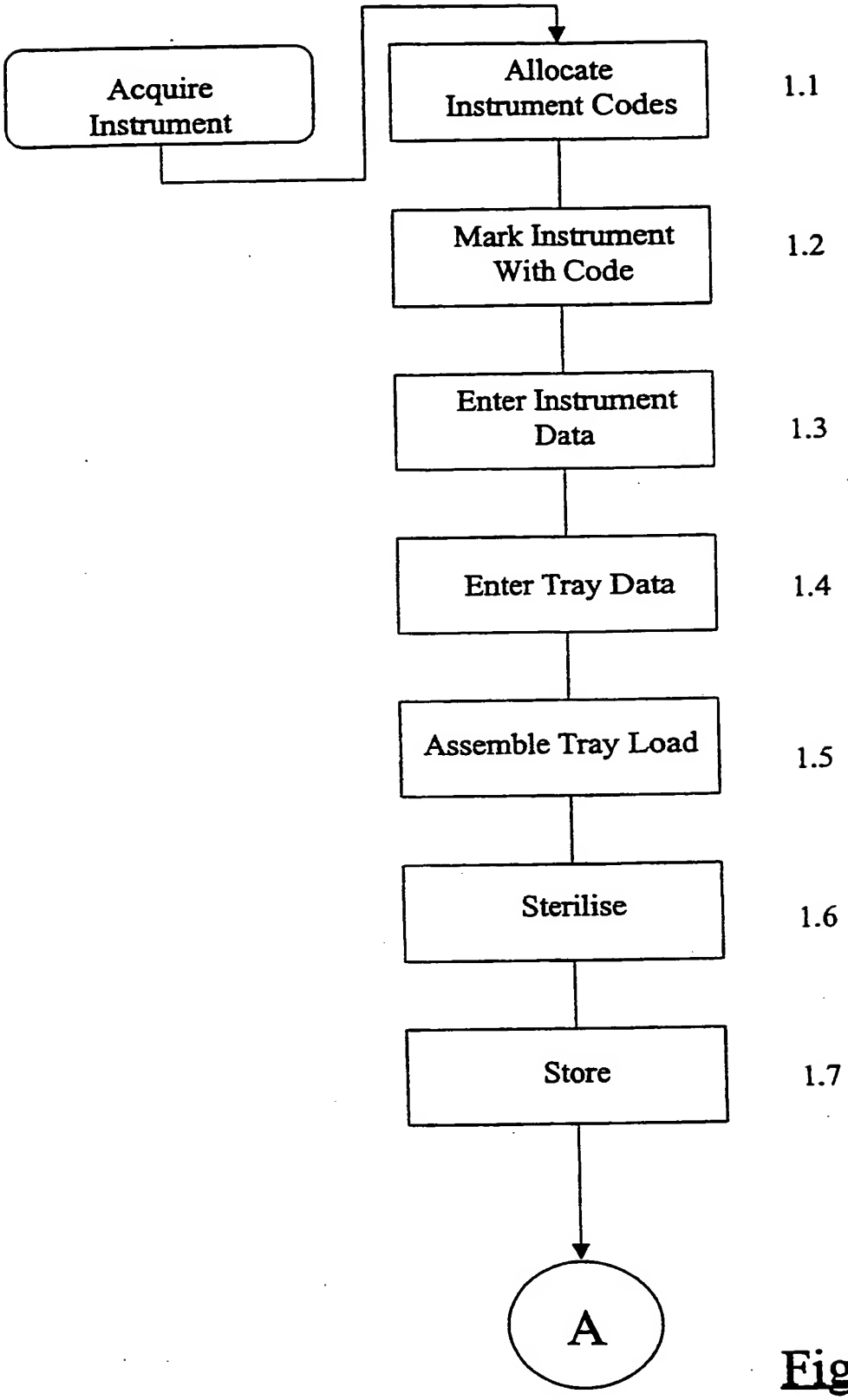

Figure 1A

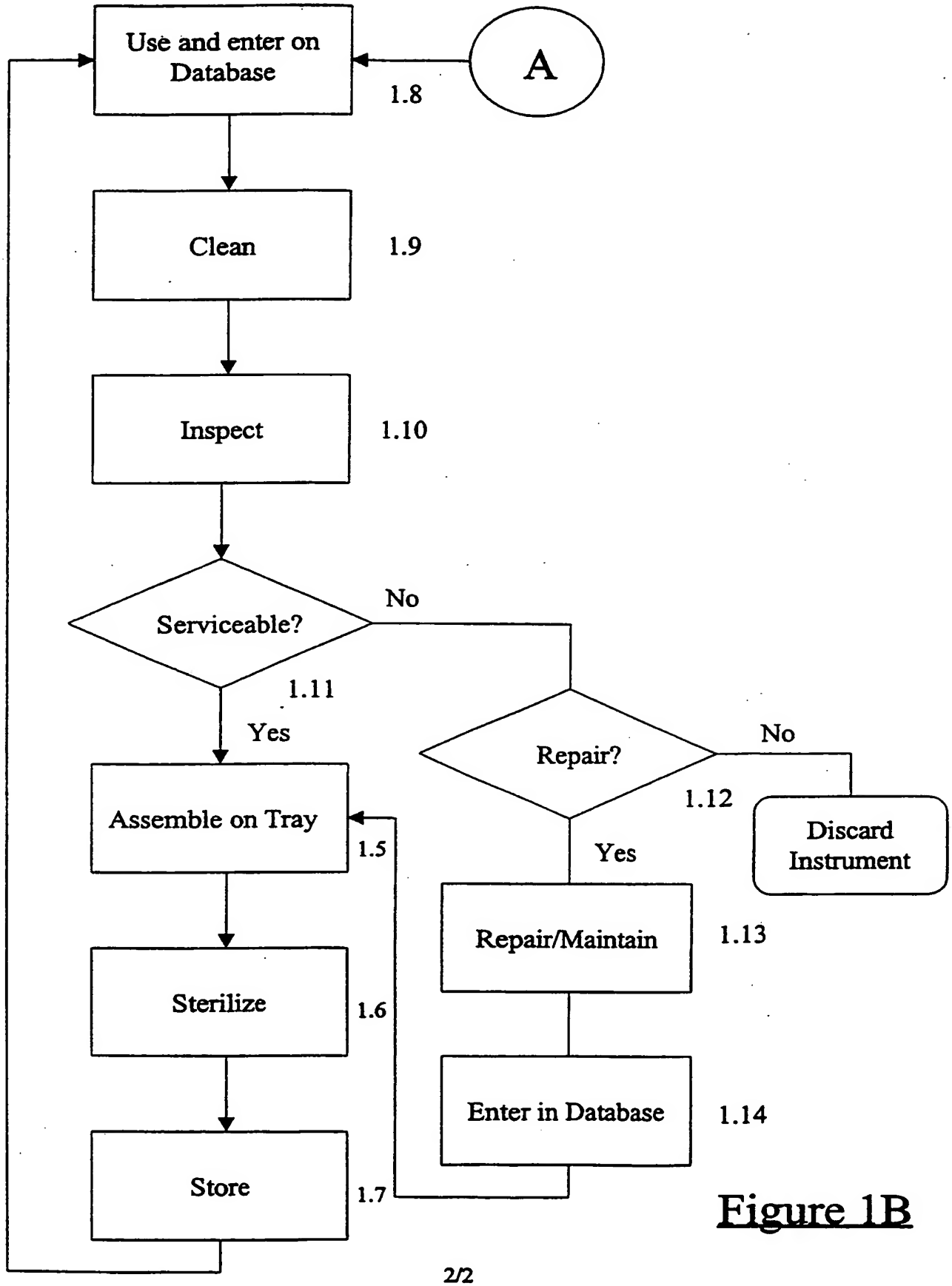

Figure 1B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 99/00492

A. CLASSIFICATION OF SUBJECT MATTER

Int Cl[6]: G06F 159/00, 19/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC G06F 159/00 19/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
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2. (SURGERY OR SURGICAL:) AND (TOOL# OR INSTRUM:) AND (IDENTIF: OR CODE) AND STERILIS:

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95/27252 A (LYNN LTD.) 12 October 1995 See whole document.	1, 2, 4, 5, 8-14
X	DE 19614719 A (AESCULAP AG) 16 October 1997. See whole document	1, 2, 12, 14
X	DE 19703822 A (INSTRUCLEAN WEST MED.) 18 June 1998 See whole document	1, 2, 12, 14

[X] Further documents are listed in the continuation of Box C

[X] See patent family annex

* Special categories of cited documents:

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Date of the actual completion of the international search	Date of mailing of the international search report
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 99/00492

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, A	FR 2770127 A (OURY CHRISTIAN) 30 April 1999 See abstract and figure 2	
A	NL 1001018 A (WENTZEL PEETENBOSCH HOLDING BV) 25 February 1997 See english abstract	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 99/00492

Information on patent family members

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member	
WO	95/27252	AU	22319/95
DE	19614719		
DE	19703822		
FR	2770127		
NL	1001018		

END OF ANNEX